

EFFICACY EVALUATION-TEAM 2
RISK ASSESSMENT & SCIENCE SUPPORT BRANCH
ANTIMICROBIAL DIVISION

Date In: 02-23-97 Date Out: 04-12-98

EPA Received Date: 12-03-97

RASSB Received Data: 16-11-98 01-28-98

Reviewed by: Bruce H. Mann Microbiologist

Lan Code: 5813-21-498 Michael E. Fry

EPA Reg. No. or File Symbol 5813-21

Product Name Tackle

Product Type Hospital Disinfectant

Company Name Clorox Company

MRID No (s): 444390-01, -02, -03, -04, -05, -06, -07, -08, -09,
and -10.

Product Manager/Reviewer & Team No.: Brennis/Hick

Submission Purpose: An amendment to add claims for basic and
additional test microorganisms and additional test viruses.

Product Formulation Liquid concentrate to be diluted for use and
a ready-to-use solution.

| ACTIVE INGREDIENT (S) | % |
|-----------------------|---|
|-----------------------|---|

| | |
|---------------------------|------|
| Sodium hypochlorite | 1.84 |
|---------------------------|------|

200.0 Introduction

200.1 Use (s)

Refer to the attached labeling pinpunched 12-03-97 and last accepted label dated 10-15-97.

200.2 Background Information

"Tackle" is registered as a disinfectant for hospital institutional, industrial, and for household uses.

The current submission is an amendment to add additional microorganisms, additional viruses, and to review a proposed label.

In support of the above claims and uses, the applicant has submitted efficacy data and proposed revised label.

All data reports are summarized below.

201.0 DATA SUMMARY

201.1 BRIEF DESCRIPTION OF TESTS

"Efficacy Reports" were developed by ViroMed Laboratories, Inc., 6101 Blue Circle Drive, Minneapolis, MN 55343. The data were generated for the Clorox Company, 7200 Johnson drive, Pleasanton, CA 94588.

"Fungicidal Reports" were developed by Hill Top Biolabs, Main and Mill Streets, Miamiville, OH 45147

- A. AOAC Germicidal Spray Products Testing of Disinfectant, Official Methods of Analysis, 15th edition, 1990.
- B. Virucidal Efficacy of Disinfectants, Product Performance, Subdivision G, DIS/TSS #7 enclosure, November 1982.
- C. AOAC Fungicidal Tests.

201.3 For results and summaries, refer to recommendations under part II and note 202.1.

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Product Name Tackle

Product Type Hospital Disinfectant

Company Name The Clorox Company

MRID No (s): 444390-01, -02, -03, -04, -05, -06, -07, -08, -09,
and -10.

Product Manager/Reviewer & Team No.: Brennis/Hicks

202.0 Recommendations

202.0 Claims Related to Human Health

202.1 Efficacy Supported by the Data

- A. The submitted data developed by the AOAC Germicidal Spray Test Method are supportive of the product effectiveness against Staphylococcus aureus, Salmonella choleraesuis, Pseudomonas aeruginosa and Streptococcus pyogenes with a ready-to-use solution in the presence of a moderate amount of soil (5% fetal bovine serum) when applied to hard nonporous surfaces when thoroughly wetted and when allowed to remain wet for a 30 seconds exposure time at room temperature.
MRID #(44390-03 and -06)
- B. The submitted data developed by the AOAC Use Dilution Test methods also are supportive of product effectiveness against Escherichia coli (0157:H7), Listeria monocytogenes, and Streptococcus pyogenes in the presence of 5% fetal bovine serum and 100 ppm of synthetic hard water when applied to hard, nonporous, surfaces and allowed to remain wet for a 5 minute exposure time at a 1:32 dilution.
MRID #(44390-04)
- C. The submitted data developed by the AOAC Germicidal Spray Tests methods are also supportive of the product effectiveness as a fungicide (pathogenic fungi) Trichophyton mentagrophytes (CDC y-68+) in the presence of 5% horse serum with an undiluted product for a 5 minute exposure time for the appropriate use areas.
MRID #(444390-09)
- D. The submitted data developed by the AOAC Germicidal Spray Tests Methods also are supportive of the product effectiveness against Escherichia coli (ATCC 35150) and Listeria monocytogenes (ATCC 19117) in the presence of 5% fetal bovine serum for an exposure time of 30 seconds for hard, nonporous, inanimate surfaces
MRID #(444390-05)
- E. The submitted virucidal efficacy data developed by the AOAC Germicidal Spray Test Method are supportive of the product effectiveness a virucide against Adenovirus Type 2 (ATCC VR-846) in the presence of 5% fetal bovine serum for a 30 second contact time for hard, nonporous, inanimate surfaces at room temperature.
MRID #(44390-01)

Effectiveness as a virucide was also demonstrated against Adenovirus Type 2 (ATCC VR-846) in the presence of 5% fetal bovine serum and 100 ppm of synthetic hard water for a 30 second contact time for hard nonporous, surfaces at a dilution of 1:32.

MRID #(444390-10)

Effectiveness was also demonstrated as a virucide against Rotavirus (Strain WA) in the presence of 5% fetal bovine serum and 100 ppm of synthetic hard water for a 30 second contact time for hard, nonporous, inanimate surfaces for a dilution of 1:32.

MRID #(444390-02)

Product effectiveness was also demonstrated as a virucide against Coxsackievirus B3 (ATCC VR-30) (Strain Nancy) in the presence of 5% fetal bovine serum for a 30 seconds contact time for hard, nonporous, surfaces with a ready-to-use solution (pump spray).

MRID #(444390-07)

Product effectiveness was also demonstrated as a virucide against Coxsackievirus B3 (ATCC VR-30) (Strain Nancy) in the presence of 5% fetal bovine serum and 100 ppm of synthetic hard water for a 30 seconds contact time for hard, nonporous, surfaces with a 1:32 dilution.

MRID #(444390-08)

203.0 Labeling comments

The following comments are applicable for the subject product "Tackle" (EPA Reg. No. 5813-21) which is pinpunched 12-03-97.

- A. On page #1, there are no adverse labeling comments.
- B. There are no adverse comments on page #2.
- C. No adverse comments on page #3.
- D. Page #4 contains no adverse comments.
- E. Page #5 no adverse comments.
- F. No adverse comments on page #6, #7, #8, #9, #10 and #11.
- G. On page #12, on the bottom of the page, after "fungus**", add "...on hard, nonporous inanimate surfaces..."
- H. No adverse comments on page #13.

surfaces..."

- H. No adverse comments on page #13.
- I. Page #14 is satisfactory.
- J. On the top of page #15, delete "...fast acting...".
- K. Page #16 appears to be satisfactory.
- L. Pages #17 and #18 appears to be satisfactory.
- M. On page #19, items #6d, after "... (Coxsackie) ...", add "...on hard, nonporous surfaces...".
- N. Page #20 appears to be adequate.
- O. On page #21, items 8 and 6, after (Coxsackie), add "on hard nonporous surfaces.
- P. Page #22 appears to be satisfactory.
- Q. Page #23 appears to be adequate.
- R. On page #24, at the top panel, following 6d, and after (Coxsackie), add "on hard nonporous surfaes".
- S. On page #25, no adverse comments.
- T. Pages #26, #27, #28, #29 and #30 appears to be satisfactory. No adverse comments.
- U. On page #31, delete the wording "powerful".
- V. Pages #32 and #33 appears to be adequate.